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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/130,041	08/06/1998	H. CRAIG DEES	PHO105	5652

7590 02/12/2007

COOK MCFARRON AND MANZO
200 W ADAMS STREET
SUITE 2850
CHICAGO, IL 60606

EXAMINER	
BARRETT, THOMAS C	
ART UNIT	PAPER NUMBER
3738	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/130,041	DEES ET AL.	
	Examiner	Art Unit	
	Thomas C. Barrett	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) *5,19,32 and 33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,11,13,14,16,17,20,21,23-28,31,35-39,68,69,71,72,77,79,80 and 82-86* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12-06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1-5,11,13,14,16,17,19-21,23-28,31-33,35-39,68,69,71,72,77,79,80 and 82-86.

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1-5, 11, 13-14, 16-17, 19-21, 23-28, 31-33, 35-39, 68-69, 71-72, 77, 79-80 and 82-86 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 20-21, 31, 35-36, 68-69 and 83-84 are rejected under 35 U.S.C. 102(e) as being anticipated by Richter et al. (6,274,614). Richter et al. discloses a method for topical treatment of diseased tissue, said method comprising the steps of: applying a PDT agent directly to said diseased tissue to form a treatment zone; purging excess agent; and applying a substantially uniform light field to said treatment zone to activate agent associated with said tissue, wherein said light penetrates said treatment zone while minimizing activation of said agent outside said treatment zone, wherein said step of purging is performed within approximately 30 minutes of said step of applying said agent and further wherein said steps of applying said agent, purging said excess

agent and applying said light field are performed within a single procedure (e.g. col. 21, line 46- col. 22, line 13).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 4, 11, 13-14, 16-17, 37-39, 71-72, 77, 79-80, 85-86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams et al. (5,576,013), in view of Richter et al. (6,274,614). Williams et al. discloses a method for treatment of disease, said method comprising the steps of: applying Rose Bengal and a chelator to diseased tissue to form a treatment zone (col. 5, line 7-col. 6, line 30); and applying light at 550 nm to said treatment zone to activate the agent associated with said tissue, wherein said light penetrates said treatment zone while minimizing activation of said agent outside said treatment zone. However Williams et al. does not disclose purging of

excess agent. Richter et al. teaches a method for topical treatment of diseased tissue, said method comprising the step of purging excess PDT agent as noted above. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the teaching of step of purging excess PDT agent, as taught by Richter et al., to a method for treatment of disease as per Williams et al., in order to that "the degree and extent of pharmacological activity can be reliably controlled" (Richter et al.- col. 9, line 66- col. 10, line 3).

Claims 23-28, and 82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams et al. (5,576,013), in view of Richter et al. (6,274,614), in further view of the admission of the present specification. Williams et al./Richter et al. discloses a method for treatment of diseased tissue, e.g. gastrointestinal tissue, however Williams et al./Richter et al. fails to disclose the use of a balloon or catheter. The specification of the present application admits "Barrett's esophagus is a perfect example of a superficial disease that is an attractive candidate for PDT as it occurs in a location that is difficult to access via conventional surgical means but is readily accessible using endoscopic catheters" The specification further admits that the use of a balloon and catheter is a "common method" (pages 5-6). It would have been obvious to one of ordinary skill in the art to combine the teaching of the use of a balloon and catheter, as admitted by the Applicant, to a method for treatment of diseased tissue as per Williams et al./Richter et al., the motivation to combine being it is an "attractive" method for disease treatments that are difficult to access. Please note that it would be obvious to use either a

compliant or non-complaint balloon, as their use is not patentably distinct from one another as admitted by the applicant in the response of January 6, 2005.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas C. Barrett whose telephone number is (571) 272-4746. The examiner can normally be reached on Mon. -Fri. from 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Thomas C. Barrett
Examiner
Art Unit 3738

TOM BARRETT
PRIMARY EXAMINER
TECHNOLOGY CENTER 3700